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EXAMINER	
SIEFKE, SAMUEL P	
ART UNIT	**PAPER NUMBER**
1797	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/649,293	MAUS ET AL.	
	Examiner	Art Unit	
	SAM P. SIEFKE	1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 March 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *26-31,33,50-52 and 54* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *26-31, 33 and 54* is/are allowed.

6)☒ Claim(s) *50 and 52* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Objections

Claim 33 is objected to because of the following informalities: Claim 33 is dependent on claim 32 which is cancelled. Examiner recommends depending claim 33 on 26. Appropriate correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 50-52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brown (USPN 5,307,263) in view of Levin et al. (USPN 5,724,580) and in further view of Cuypers (USPN 5,396,886).

Brown discloses a modular based microprocessor-based health monitoring system that comprises: a glucose monitor that comprises a test strip reader for reading a test strip carrying a sample of biological fluid (fig. 1, ref. 16; col. 7, lines 38-39; col. 17, lines 52-60) and obtaining test results based on the sample or biological fluid and calibration data specific to the test strip (col. 17, lines 9-51); a memory reading device (12) functionally connected (14; col. 7, lines 30-37) to the test strip reader and operable for reading the calibration data from a memory device (col. 17, lines 9-51); a data drive (10) functionally connected (18 to the test strip reader and operable for writing the test results to a memory storage device (EEPROM 94; col. 15, line 65-col. 17, line 8). Brown states that the blood glucose monitor 16 being connected to the data management unit 10 by cable 18 but states that it may be preferable to construct the

blood glucose monitor 16 as a plug-in unit that is placed in a recess or other suitable opening or slot in data management unit 10. Then goes on to state regardless of the manner in which the blood glucose monitor 16 is interconnected with the data management unit 10, both that interconnection and cable 14 are configured for serial data communication between the interconnected devices (col. 7, lines 38-47). Brown discloses a health report server (54) operable for: receiving the test results and additional diagnostic information (col. 11, lines 18-40; col. 11, line 65- col. 12, line 15); compiling a health report based on the test results and the additional diagnostic information (col. 12, line 65- co. 13, line 15; col. 15, lines 19-44); and transmitting the heath report (col. 12, lines 16-28). Brown further discloses a computer station operable (62) for reading the test results from the memory storage device, establishing a network connection with the health report server, receiving the additional diagnostic information, transmitting the test results and the diagnostic information to the health report server, receiving the health report from the health report server and printing the health report (col. 12, lines 29-col. 13, line 46; col. 13, line 60- col. 14, line 8). Regarding claim 2, Brown discloses program instructions stored in data management unit 10 and program instruction stored in program cartridge 42 of handheld microprocessor unit 12 to enable the system to display statistical and trend information either in graphic or alphanumeric format (col. 18, lines 43-47) an also allow trend information to be reported in the health report (col. 11, lines 30-35; col. 19). Brown teaches the health reports are secured on a doctor's computer and the Examiner states that the computer is secure because of the secure manner in which physicians computers are kept with password protection.

Brown does not teach measuring blood lipid levels; additional diagnostic information including: a medical risk index, a recommended weight loss, a five year risk of heart attack, a ten year risk of heart attack, a cardiac age, an extended age a risk of stroke; the health report including a data sheet for newly prescribed drugs and the other currently prescribed drugs; a target weight, a schedule for future testing, a health assessment summary, a coronary risk assessment, a dietary guidelines to lower cholesterol.

Levin teaches a system of generating prognosis and therapy reports for coronary health management that comprises inputting parameters of a user into a hand-held monitor that includes general information such as doctors ID number, patient's assigned ID number, birth date, sex, height, weight, coronary status, blood pressure, known allergic conditions, cholesterol levels, glucose levels, present drug regimens, smoking habits and exercise regimes (col. 5, lines 1-9). This information is then transferred to a processing server which computes by algorithm and interprets the history of the patient and proceeds to issue a course of action and treatment (col. 5, lines 26-37). The patient report is printed as seen in figure 25a and 25b which includes a medical risk category, in this example the patient is in the highest risk category for a cardiac event in the next year. The report breaks down, lipid profile, antihypertensive therapy, antithrombotic therapy, diabetes, smoking cessation, ideal body weight, program of regular exercise, etc where each therapy describes in depth the patients habits or the addition of a newly prescribed drug and other currently prescribed drugs. It would have been obvious to one having an ordinary skill in the art at the time of the invention to

modify Brown to employ a blood lipid level along with the glucose levels because this provides more knowledge a physician needs to diagnose a patients problems. This further provides the information necessary to perform other tests such as diagnosing hypolipidemic therapy. It would have been obvious to modify Brown to include essential patient information such as gender, sex, height, age, weight, blood pressure because these are essential vital information used to make up a heath report of a patient. Regarding claim 29, it would have been obvious to one having an ordinary skill in that art to modify Brown to employ a diagnostic result that included a medical risk index which puts a patient in a risk category because this raises patient awareness of a problem and therefore increase the chances that a patient will take an action to prevent the future problem diagnosed by the physician. Regarding claim 30, it would have been obvious to one having an ordinary skill in the art to modify Brown to employ a diagnostic information relating to newly prescribed drug and other currently prescribed drugs and if there are any cross-reaction between the newly prescribed drug and the currently prescribed drug because this would prevent placing the patient in a potentially life-threatening event caused by the cross-reaction between two drugs. Regarding claim 31, it would have been obvious to one having an ordinary skill in the art to modify Brown to employ in the health report to include a heath assessment summary because this raises patient awareness of a problem and therefore increase the chances that a patient will take an action to prevent the future problem diagnosed by the physician. This type of health assessment is well known in the art to be employed in patient health reports.

The modified Brown teaches a one year cardiac risk assesment.

Cuypers teaches a method for predicting coronary heart disease that comprises collecting data that includes glucose, total cholesterol, triglycerides, age of patient, blood pressure, patient weight, etc and then combining the data to output a five and 10 year cardiovascular risk factor (abstract, col. 6, lines 10- col. 7). Therefore it would have been obvious to one having an ordinary skill in the art at the time of the invention to modify the modified Brown to extrapolate to a five and 10 year risk of heart attack to give a patient more information regarding their health. This would also provide the patient a preventative health schedule in order to reduce the risk of a cardiac event in the future.

Allowable Subject Matter

Claim 26-31, 33 and 54 are allowed.

Response to Arguments

Applicant's arguments filed 3/16/09 have been fully considered but they are not persuasive. Applicant argues, “Claims 50 and 52 are allowable for the same reason as claim 26, since they recite a second sample to be tested. Claim 51 and 55 are allowable at least by virtue of their dependence on claims 50 and 52, respectively. Claims 32, 53, and 55 have been canceled.” Claim 50 and 52 only requires a first and second biological fluid or tissue sample be tested. The limitations of the indicated allowable subject matter of claim 32 where not incorporated into either claim 50 or 52. The prior art tests multiple samples, therefore the claim is anticipated in view of the obvious

rejection as seen above. The allowable subject mater included the test strip reader is operable for reading a second type of test strip carrying a second sample of biological fluid or tissue and obtaining health-related test results based on the second sample of biological tissue or fluid and calibration data specific to the second type of test strip, further comprising: a second memory reading device functionally connected to the test strip reader and operable for reading calibration data from a second memory device corresponding to the second type of test strip. These limitations are absent from claim 50 and 52.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SAM P. SIEFKE whose telephone number is (571)272-1262. The examiner can normally be reached on M-F 7:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on 571-272-1700. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Samuel P Siefke/
Primary Examiner, Art Unit 1797